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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,723	06/24/2003	Mogens Wumpelmann	10339.200-US	3277

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EXAMINER

KOSSON, ROSANNE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/603,723	Applicant(s) WUMPELMANN ET AL.	
	Examiner Rosanne Kosson	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12-16 is/are pending in the application.
 4a) Of the above claim(s) 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 12-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on May 4, 2005 has been received and entered. Claims 1-3 have been amended. Claims 10 and 11 have been canceled, and claims 15 and 16 have been added. Accordingly, claims 1-7 and 12-16 are examined on the merits herewith.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

Regarding Applicants' claim of priority to Danish application PA 2002 01021, filed on July 1, 2002, and to U.S. provisional application, 60/393,275, filed on July 1, 2002, Applicants comment that these applications disclose the use of several protein hydrolysates in the fermentation medium is noted. Nevertheless, as previously noted, these applications are concerned with a method of improving the yield of a recombinant peptide produced in fermentation by adding monopropylene glycol to the medium, to inhibit the precipitation or crystallization of the recombinant protein. The subject matter of the instant claims is not disclosed in these applications. Accordingly, Applicants may wish to correct their priority claim.

Claim Rejections - 35 USC § 102

In view of Applicants' amendments to the claims, the rejection under 35 U.S.C. 102(b) is withdrawn.

Claim Rejections - 35 USC § 103

Claims 1-7 and 12-14 are again rejected, and claims 15 and 16 are rejected, under 35 U.S.C. 103(a) as being unpatentable over Huchette et al. (US 4,766,070).

This rejection was discussed in the previous Office action.

In reply to Applicants' arguments, Applicants note that Huchette does not disclose or suggest prehydrolyzing the complex N-source to a degree of 1-20%. But, Applicants have not shown that prehydrolyzing the complex N-source to various degrees within the range of 1-20% results in improved yields of a protease or peptidase fermentation product. Example 12 teaches that when the N-source is hydrolyzed 2.9% before sterilization, compared to 51% hydrolysis before sterilization, a significantly improved yield and reduced product degradation result. This result, however, is obtained with only one prehydrolyzed N-source- 2.9% hydrolysis. Improved results are also shown in the production of an α -amylase, using a N-source that was prehydrolyzed to a degree of 19.5%. But, in this case, it is not a protease or peptidase that is produced, i.e., an enzyme that might itself be capable of breaking down the N-source for use by the fermenting microorganism. Therefore, although Applicants have shown that a low degree of N-source hydrolysis, about 3%, can improve product yields for a protease, it cannot be predicted that this result applies to other enzymes and other degrees of hydrolysis above 3% to 20%.

Nevertheless, if Applicants can present such data for other enzymes and other degrees of hydrolysis of 20% and below, they will be considered.

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In view of the foregoing, the rejection of record is maintained.

No claim is allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

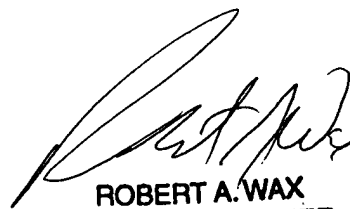
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner
Art Unit 1651

rk
2005-05-13



ROBERT A. WAX
PRIMARY EXAMINER
Art Unit 1653